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10/523,121	01/24/2005	Stanley George Bonney	PG4885USw	8414

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EXAMINER	
DIXON, ANNETTE FREDRICKA	
ART UNIT	**PAPER NUMBER**
3771	

NOTIFICATION DATE	DELIVERY MODE
04/30/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/523,121	BONNEY ET AL.	
	Examiner	Art Unit	
	Annette F. Dixon	3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 January 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7 and 9-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7 and 9-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This Office Action is in response to the amendment filed on January 14, 2009. Examiner acknowledges claims 1-7 and 9-22 are pending in this application.

Claim Objections

2. Claim 1 is objected to because of the following informalities: Specifically, claim 1 recites "simultaneous delivery from each dispenser"; however, the claim language and drawings only support a single dispenser with a plurality of medicament containers. Thus, it appears the "each dispenser" language lacks antecedent basis. Appropriate correction is required.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-7, 9, and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Cox et al. (6,234,167).

As to Claim 1-4, Cox discloses a medicament dispenser device (121) for use in the delivery of a multi-component combination medicament product, the device comprising: a first medicament container (37) containing a plural co-formulation

compatible medicament components; a first release means for the contents first medicament container for delivery thereof (35); at least one further medicament container (137), each containing at least one co-formulation incompatible medicament component; and at least one further release means for releasing the contents of each at least one further medicament container for delivery thereof (135), wherein the at least one co-formulation incompatible medicament component is kept separate from the plural co-formulation compatible components until the point of release thereof for delivery in combination. Regarding the co-formulation limitation, Cox discloses the medicament containers may include two or more components mixed together before the material is volatilized. (Column 9, Lines 52-66 and Figure 3).

As to Claim 5 and 10, Cox discloses an aerosol generator (121) is an inhaler device. (Column 3, Lines 45-60).

As to Claim 6, Cox discloses the first medicament container and the second medicament container may be similar or different. Specifically, Cox discloses the first and second medicament container may be held at the same or different pressures to facilitate the delivery of the medicament to the patient. Thus inherently, the first medicament container may be similar to the second medicament container when the co-formulations are held a the same pressure or the first medicament container may be different from the second medicament container when the co-formulations are held at different pressures. (Column 8, Line 47 thru Column 9, Line 12).

As to Claim 9, Cox discloses a mixing chamber (29) including a first inlet (the location between the release means 35 and element 29) for receiving the released

contents of the first medicament container (37), a second inlet (the location between the release means 135 and element 29) for receiving the released contents of the second medicament container (137), and an outlet (the location between element 29 and mouthpiece 53) for the delivery of combination medicament product therefrom.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 11-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cox et al. (6,234,167) in view Marfat et al. (6,559,168).

As to Claims 11-22, Cox discloses a medicament device, yet does not expressly disclose the recited medicaments. However at the time the invention was made the use of the recited medicaments was well known. Specifically, Marfat discloses all the recited medicaments are known and used in the treatment of respiratory diseases such as asthma, chronic bronchitis, and chronic obstructive pulmonary disease. (Column 209-256). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Cox to include the medicaments, as taught by Marfat, to be used in the treatment of respiratory diseases.

Response to Arguments

7. Applicant's arguments filed October 2, 2007 have been fully considered but they are not persuasive. Applicant asserts the prior art made of record does not disclose or teach "release means are mechanically or fairly suggest a first and second release means that are coupled together, thereby enabling simultaneous delivery of medicament from each dispenser in response to a single patient actuation step." Examiner respectfully disagrees with Applicant's assertion. The device of Cox discloses two valves (35 and 135) capable of being utilized with simultaneously (Column 8, Lines 47-65). Regarding the mechanical coupling of the valves (35 and 135). Webster's dictionary defines "mechanically" as "of or relating to machines or tools, operated or produced by machine". Intrinsically, this definition discloses the mechanical operation of the valves (35 and 135) thru the use of the machinery of the control device (43). Finally, regarding the "single patient actuation step", Cox discloses the signal for activation is delivered to the control device (43) via the air flow detecting device (51). (Column 5, Lines 50-62). Therefore, in light of the aforementioned reasoning, the rejection of the claims has been maintained.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 1-7, and 9-22 are rejected as best understood by the Examiner under 35 U.S.C. 103 (a) as being unpatentable over Haikarainen et al. (6,810,873) in views of Dean et al. (2002/0128216).

As to Claim 1, Haikarainen discloses a medicament dispenser device (Figure 1) for use in the delivery of a multi-component combination medicament product (Summary), the device comprising: a first medicament container (1) containing a medicament component, a release means (7b) for releasing the contents of the first medicament container (1) for delivery thereof; at least one further medicament container (2), containing at least one co-formulation incompatible medicament component (Column 1, Line 58 thru Column 2, Line 35) ; and a second release means (7a) for releasing the contents of the further medicament container (2) for the delivery thereof, wherein the first release means (7b) and the second release means (7a) are mechanically coupled together, thereby enabling simultaneous delivery of medicament from each container in response to a single patient actuation step (the depression of the cover 4 as described in Column 5, Lines 10-15); where the in compatible medicament component (Column 1, Line 58 thru Column 2, Line 35) is kept separate from the compatible components until the point of release thereof for delivery in combination (from the mouthpiece 11 via air channel 12). Yet, Haikarainen does not expressly disclose two separate release means that are mechanically formed, nor does Haikarainen disclose the use of a plurality of co-formulations of medicament. However, at the time the invention was made the use of a two separate release means and the

use of a plurality of co-formulations of medicament were known. Regarding the mechanically coupled language, the device of Haikarainen discloses two release means that are integrally formed. Yet, it would have been obvious to one having ordinary skill in the art at the time the invention was made to form the release means (7a and 7b) separately , since it has been held that constructing a formerly integral structure in various elements involves only routine skill in the art. *Nerwin v. Erlichman*, 168 USPQ 177, 179. Regarding the use of a plurality of medicament co-formulations, Haikarainen discloses the two containers contain medicaments with different active ingredients, specifically a bronchodilator in one container and an anti-inflammatory drug in another container (Column 2, Lines 20-35); however, Dean teaches different types of bronchodilator and anti-inflammatory drugs that can have multiple co-formulations within each type for the delivery of medicament. Specifically, Dean teaches the co-formulation of salbutamol and terbutaline as a bronchodilator co-formulation drug and prednisone and methylprednisolone as an anti-inflammatory co-formulation drug for providing anti-asthma medication to a patient for providing quick-relief and long term preventative medications. (Paragraph 0063). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Haikarainen to include a plurality of medicament co-formulations as taught by Dean in order to provide co-formulation medicaments capable of providing effective anti-asthma treatment to a patient.

As to Claims 2, and 3, the system of Haikarainen as modified by Dean teaches the first container having two co-formulations and the second container having an

additional co formulation compatible with the medicament components. Specifically, Dean teaches the co-formulation of salbutamol and terbutaline as a bronchodilator co-formulation drug and prednisone and methylprednisolone as an anti-inflammatory co-formulation drug, in addition to numerous other drugs for providing anti-asthma medication to a patient for providing quick-relief and long term preventative medications. (Paragraph 0063).

As to Claim 4, the system of Haikarainen as modified by Dean teaches the first container having two co-formulations and the second container having two additional co formulation compatible with the medicament components. Yet, does not expressly disclose the use of a third medicament container. However, Dean teaches additional types of medicaments that may be administered in combination or in conjunction with known asthma medications, such as sustain release theophyllines, short acting theophyllines and anticholinergics. Intrinsically, as these types of medicaments may be administered in combination or in conjunction an additional medicament container with release means would have been obvious, since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8.

As to Claim 5, Haikarainen discloses the use of a multi-dose powder inhaler. (Column 2 Lines 20-21).

As to Claim 6, Haikarainen discloses the first and second medicament containers (1 and 2, respectively) are of similar type (Figure 1).

As to Claim 7, Haikarainen discloses the first and second medicament containers (1 and 2, respectively) are of similar type (Figure 1); however, a change in size or shape of the medicament containers would have been obvious based on the type of medicament being utilized. Since, a change in size is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 105 USPQ 237 (CCPA 1955) and a change in form or shape is generally recognized as being within the level of ordinary skill in the art, absent any showing of unexpected results. *In re Dailey et al.*, 149 USPQ 47.

As to Claim 9, Haikarainen discloses the first and second medicament containers (1 and 2, respectively) dispense their medicament into the projection 10 to enable mixing of the medicament within the mouthpiece (11) prior to being deposited in the lungs of the patient. (Column 50-55).

As to Claims 10-22, Dean teaches the co-formulation of salbutamol and terbutaline as a short acting Beta-2 agonists bronchodilators drugs, prednisone and methylprednisolone as cortiocosteriods anti-inflammatory drugs, ipratoprium as an anticholinergics, and theophyllines. (Paragraph 0063).

Response to Arguments

10. Applicant's arguments filed January 14, 2009 have been fully considered but they are not persuasive. Applicant asserts the prior art made of record does not disclose or teach a first and second release means that are mechanically coupled together. With respect to this assertion, the claim limitations recite the release means are

"mechanically coupled together" there is no recitation of the release means to be controlled by the mechanical coupling, rather the release means is recited to be controlled "in response to a single patient actuation step". As seen in Figure 3 of Cox, the first medicament container (37) has a first release means (35) and the second medicament container (137) has a second release means (135). These release means are mechanically coupled together in a structural orientation by the connection piece (29) which extends between the first and second release means. The actuation of these release means (35 and 135) is directed by the control member (43) so that the control of the valve can occur either simultaneously or independent of each other. (Column 8, Lines 47-65 and Column 5, Lines 50-62). Thus the rejection of the prior art is maintained.

Conclusion

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Haikarainen et al. (6,810,873) discloses an additional multi-dose powder inhaler and Dean et al. (2002/0128216) discloses additional medicaments used in inhalers.

12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Annette F. Dixon whose telephone number is (571) 272-3392. The examiner can normally be reached on Monday thru Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Annette F Dixon
Examiner
Art Unit 3771

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